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Paper No. 19

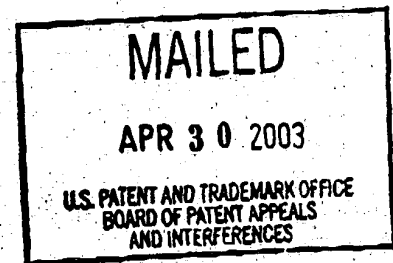
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte JEAN-MARC PAYRAT,
CLAES F. HOGMAN,
JACK DEBRAUWERE, and
JEAN MARIE MATHIAS

Appeal No. 2002-0090
Application No. 09/268,405

ON BRIEF¹



Before WILLIAM F. SMITH, ADAMS and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on the appeal under 35 U.S.C. § 134 from the
examiner's final rejection of claims 37-43. The only other pending claims (claims
44 and 45) were withdrawn from consideration as drawn to a non-elected
invention.

¹ We note that appellants waived their request for oral hearing. Accordingly, we considered this
appeal on Brief.

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Claim 37² is illustrative of the subject matter on appeal and is reproduced below:

37. An aqueous red blood cell storage solution comprising a first distinct solution and a second distinct solution wherein:

the first distinct solution consists essentially of sodium citrate, sodium diphosphate, sodium phosphate dibasic, adenine, and mannitol, the aqueous storage solution including a sufficient amount of sodium diphosphate and sodium phosphate dibasic so as to maintain, when combined with the second distinct solution, a 2,3 diphosphoglycerate concentration in the red cells stored at refrigeration temperatures to at least 80% of an initial concentration for at least 21 days; and

the second distinct solution consists essentially of at least one sugar chosen from the group consisting of dextrose and fructose.

The references relied upon by the examiner are:

Deindoerfer et al. (Deindoerfer)	3,874,384	Apr. 1, 1975
Meryman et al. (Meryman)	5,250,303	Oct. 5, 1993
European Patent Application: Carmen et al. (Carmen)	0 142 002	May 22, 1985
Costa de Oliveira et al. (Oliveira), "Thermal degradation products of sugars in alkaline pH," <u>Chem. Abst.</u> , Abst. No. 96:177792 (1981)		
Del Pilar Buera et al. (Buera), "Nonenzymatic browning in liquid model systems of high water activity: kinetics of color changes due to caramelization of various single sugars," <u>Chem. Abst.</u> , Abst. No. 107:132797 (1987)		

GROUND OF REJECTION

Claims 37-43 stand rejected under 35 U.S.C. § 103 as obvious over Meryman in view of Deindoerfer and any one of Buera, Oliveira or Carmen.

We affirm.

² We note the claim 37 was incorrectly reproduced in appellants' appendix of claims. Specifically the word "at" was deleted prior to the words "least 80%."

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CLAIM GROUPING

According to appellants (Brief, pag 6), "[a]ppellants argue for the separate patentability of each of the independent claims separate and apart from each other set forth in detail below pursuant to the requirements of 37 C.F.R. § 1.192(7), unless otherwise specified." As set forth in 37 CFR § 1.192(7) (emphasis added):

For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable. Merely pointing out [the] differences in what the claims cover is not an argument as to why the claims are separately patentable.

While appellants have pointed out the differences in what the claims cover (Brief, pages 6-7), appellants provide no separate explanation as to why the claims of the group are believed to be separately patentable. At best, appellants note (Brief, page 10) that claims 37-40 and 43 are independent claims that require varying amounts of ingredients. However, rather than provide an argument regarding these limitations, appellants limit their argument to the requirement in each of the independent claims that the solution be "derived from two distinct or separate solutions or parts...." See e.g., Brief, pages 10 and 11. Accordingly, we interpret appellants' statement "unless otherwise specified" together with the lack of argument with regard to any individual claim to mean that the claims stand or fall together. Accordingly, we limit our discussion to

representative independent claim 37. Claims 38-43 will stand or fall together with claim 37. In re Dance, 160 F.3d 1339, 1340 n.2, 48 USPQ2d 1635, 1636 n.2 (Fed. Cir. 1998).

DISCUSSION

According to the examiner (Answer, page 5), Meryman discloses a red blood cell storage solution consisting of sodium citrate, sodium diphosphate, sodium phosphate dibasic, adenine, mannitol and glucose. The examiner finds (Answer, page 6), however, that Meryman does not divide the "components of the composition into two solutions...." To make up for this deficiency, the examiner finds with reference to Oliveira, Buera and Carmen that sugars such as dextrose degrade during heat sterilization. Id. Therefore, the examiner relies on Deindoerfer's disclosure of "the separation of a blood cell storage solution into two parts for purposes of heat sterilization." Id. According to the examiner (id.) Deindoerfer discloses a first solution "containing dextrose and DHA may be heat sterilized at acid pH, 3.8-4.2, while the remaining ingredients may be sterilized [as part of a second solution] at a higher pH than the dextrose, DHA components. The two solutions are mixed prior to use."

Based on this evidence the examiner finds (Answer, pages 6-7), since

it is known to divide the components of a blood storage solution into two solutions prior to heat sterilization in order to have solutions with distinct pHs which can stabilize heat labile components prior to autoclaving.... The division of the blood storage solution disclosed in ... [Meryman] into two parts, one of which contains the components other than glucose and one which contains glucose, would have been [prima facie] obvious [to a person of ordinary skill in the art at the time the invention was made].

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In response, appellants argue (Brief, pag 11), "[a]pp llants hav demonstrated that storag solutions embodying the aqu ous red blood cell storage solution of the present invention have maintained the concentration of 2,3-BPG [sic] in the red blood cells at about 80 to about 110% of the initial concentration after 21 days." However, as the examiner points out (Answer, pages 10-11), "no comparison has been made or argued with the prior art solutions of ... [Meryman] which have all of the claimed components in the claimed ranges of concentration in various red blood cell storage solutions disclosed in Table 2 and in the examples."

As set forth in In re Freeman, 474 F.2d 1318, 1324, 177 USPQ 139, 143 (CCPA 1973):

In order for a showing of "unexpected results" to be probative evidence of non-obviousness, it falls upon the applicant to at least establish: (1) that there actually is a difference between the results obtained through the claimed invention and those of the prior art; and (2) that the difference actually obtained would not have been expected by one skilled in the art at the time of the invention.

In this regard, we note that Meryman discloses (column 4, lines 13-20):

This invention significantly improves the procedure for storing red blood cells ... by providing method that lead to reduction or elimination of adenine from the storage solution, improvement of red cell morphology, reduction of hemolysis, increases in the intracellular levels of ATP and 2,3 DPG and maintenance of said levels at or above physiological concentrations for extended period of time.

According to Meryman (column 7, lines 11-13), "[t]he terms are meant to apply to storage periods of about or greater than 30-60 days, in most cases greater than 90, or even greater than 120-160 days." For emphasis, we note that figure 5 of

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Meryman illustrates that 2,3 DPG is maintained at level above the initial value for at least 4 weeks, using ARC8. ~~While ARC8 does not contain mannitol (see~~ Meryman, column 8, Table 2), as the examiner points out, there is no evidence of record to demonstrate that similar results would not be expected to have been obtained with the use of ARC30 (see id.) which contains mannitol.

Appellants also argue (Brief, page 11) that Meryman teaches away from the separation of a blood storage solution into two distinct solutions:

Meryman fails to disclose a red blood cell storage solution that contains distinct and separate solution components as required by the independent claims. What Meryman clearly emphasizes is to adjust the pH level of a solution and ~~not to provide a solution that has physically distinct and separate solution components in order to increase the storage capability of the solution.~~ In this regard, Meryman clearly teaches away from the two distinct and separate solution component features of the aqueous red blood cell storage solution as required by the independent claims. [Emphasis removed].

In response, the examiner argues (Answer, page 11), Meryman "does not teach away from the division of a red blood cell solution into two or more distinct solutions. The reference is merely silent with respect to this element. Silence is not synonymous with 'teaching away'...."

In addition, appellants do not point out, and we do not find, any description in Meryman of a sterilization method. Therefore, a person of ordinary skill in the art would be expected to follow art-recognized methods of sterilization. In this regard, we note that Deindoerfer teaches filter sterilization is more difficult and expensive than heat sterilization. Deindoerfer, column 5, lines 28-34. As the examiner explains (Answer, page 9), Deindoerfer discloses an alternative to

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filter sterilization, wherein "heat sterilization of components of the [blood storage] solution which are labile during heat sterilization of the complete solution may be performed by division of the solution to permit separate pH control of the separated solutions prior to heating." Note, for example, that Buera teaches "[l]owering of pH inhibited caramelization browning [degradation] of sugar solns" during heat treatment, thus a sugar (dextrose) solution is just the kind of heat labile component that according to Deindoerfer should be separately sterilized.

In this regard, we recognize that Meryman discloses (column 7, line 68 to column 8, line 5) that "[e]xamples of biologically compatible buffered solution[s] that raise the intracellular pH of a red blood cell, which are used in accordance with this invention, include ... solutions that contain substantially no chloride ion and that have a pH between 5 and 9.0, generally between 7.4 and 7.5."

However, given the recognition that glucose solutions of alkaline pH degrade when heat sterilized, we agree with the examiner (Answer, page 9) that a person of ordinary skill in the art would have been motivated to use the sterilization method set forth by Deindoerfer to heat sterilize the blood storage solution as opposed to the more difficult and expensive filter sterilization methodology known to those of ordinary skill in the art.

Accordingly, we agree with the examiner (Answer, page 12), Deindoerfer "generically teach division of blood storage solutions into two solutions in order to permit separate pH control for heat sterilization.... Thus, the separation of components in a blood preservative solution prior to heat sterilization to permit maintenance of the solutions at distinct pHs, where the more heat labile

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components is clearly taught." "The test for obviousness is not express suggestion of the claimed invention in any or all of the references but rather what the references taken collectively would suggest to those of ordinary skill in the art presumed to be familiar with them." In re Rosselet, 347 F. 2d, 847, 851, 146 USPQ 183, 186 (CCPA 1965).

For the foregoing reasons, we are not persuaded by appellants' argument (Brief, page 15) that there is no motivation to combine the references.

Furthermore, we are not persuaded by appellants' argument that it would have been "obvious to try" separating blood storage solutions into two separate solutions. As discussed above, Deindoerfer teaches the separation of a blood storage solution into two separate solutions to facilitate sterilization. Appellants have offered no explanation as to why a person of ordinary skill in the art would not have had a reasonable expectation of success in separating the Meryman solution into two separate solutions to facilitate sterilization, while avoiding degradation of the glucose component.

Therefore, it is our opinion that the examiner provided the evidence necessary to meet her burden³ of establishing a prima facie case of obviousness. As a result, the burden of coming forward with evidence or argument was properly shifted to the appellants. In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). In our opinion appellants failed to meet their burden. Accordingly, we affirm the rejection of claim 37 under 35 U.S.C. §

³ The initial burden of presenting a prima facie case of obviousness rests on the examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992).

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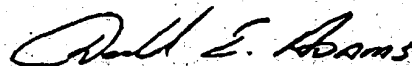
103 as obvious over Meryman in view of Deindoerfer and any one of Buera,

Oliveira or Carmen. As discussed supra claims 38-43 fall together with claim 37.

~~The time period for taking any subsequent action in connection with this~~
appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED


William F. Smith
Administrative Patent Judge


Donald E. Adams
Administrative Patent Judge


Demetra J. Mills
Administrative Patent Judge

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